F755

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§483.45 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.70(f). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

§483.45(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

§483.45(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--

§483.45(b)(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

§483.45(b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

§483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

INTENT §483.45(a) and (b)(1), (2), and (3)

The intent of this requirement is that:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist;
- The facility utilizes only persons authorized by state or local, regulation, or other guidance to administer medications during the course of employment by a facility;
- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, guide development and evaluation of pharmaceutical services procedures, and help the facility identify, evaluate, and resolve pharmaceutical concerns which affect resident care, medical care or quality of life such as the:
  - Provision of consultative services by a licensed pharmacist as necessary; and
  - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]).
- The facility, in coordination with the licensed pharmacist, provides for:
  - A system of medication records that enables periodic accurate reconciliation and accounting for all controlled medications;
  - Prompt identification of loss or potential diversion of controlled medications; and
  - Determination of the extent of loss or potential diversion of controlled medications.

NOTE: Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

DEFINITIONS §483.45

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

"Acquiring medication" is the process by which a facility requests and obtains a medication.

"Biologicals" are made from a variety of natural sources—human, animal, or microorganisms. Biologicals are used to treat, prevent, or diagnose diseases and medical conditions. They may include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

"Controlled Medications" are substances that have an accepted medical use (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence.

"Dispensing" is a process that includes the interpretation of a prescription; selection, measurement, and packaging or repackaging of the product (as necessary); and labeling of the medication or device pursuant to a prescription/order.

"Disposition" is the process of returning and/or destroying unused medications.

"Diversion of medications" is the transfer of a controlled substance or other medication from a lawful to an unlawful channel of distribution or use, as adapted from the Uniform Controlled Substances Act.

"Pharmaceutical Services" refers to:

- The process (including documentation, as applicable) of receiving and interpreting prescriber's orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, administering, monitoring responses to, using and/or disposing of all medications, biologicals, chemicals (e.g., povidone iodine, hydrogen peroxide);
- The provision of medication-related information to health care professionals and residents;
- The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and
- The provision, monitoring and/or the use of medication-related devices.

"Pharmacy assistant or technician" refers to the ancillary personnel who work under the supervision and delegation of the pharmacist, consistent with state requirements.

"Receiving medication"—for the purpose of this guidance—is the process that a facility uses to ensure that medications, accepted from the facility's pharmacy or an outside source (e.g., vending pharmacy delivery agent, Veterans Administration, family member), are accurate (e.g., doses, amount).

"Reconciliation"—for the purpose of this guidance—refers to a system of recordkeeping that ensures an accurate inventory of medications by accounting for controlled

medications that have been received, dispensed, administered, and/or, including the process of disposition.

Guidance §483.45

The provision of pharmaceutical services is an integral part of the care provided to nursing home residents. The management of complex medication regimens is challenging and requires diverse pharmaceutical services and formal mechanisms to safely handle and control medications, to maintain accurate and timely medication records, and to minimize medication-related adverse consequences or events. The overall goal of the pharmaceutical services system within a facility is to ensure the safe and effective use of medications.

Preventable medication-related adverse consequences and events are a serious concern in nursing homes. The U.S. Department of Health and Human Services (HHS) Office of the Inspector General issued a report in February 2014, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries (OEI-06-11-00370). The OIG found that one in three SNF residents experienced an adverse event or temporary harm event. Thirty-seven percent of these adverse events were related to medications and 66% of all medication-related events were preventable. Medication-related adverse events included excessive bleeding due to anticoagulant use without adequate monitoring and acute hypoglycemia. Consequences of medication-related adverse events included a prolonged SNF stay, hospitalization, life sustaining interventions, permanent harm, and death.

Factors that increase the risk of adverse consequences associated with medication use in the nursing home setting include complex medication regimens, numbers and types of medication used, physiological changes accompanying the aging process, as well as multiple comorbidities.

The consultative services of a pharmacist can promote safe and effective medication use. A pharmacist, in collaboration with facility staff, establishes, evaluates and coordinates all aspects of pharmaceutical services provided to all residents within a facility by all providers (e.g., pharmacy, prescription drug plan, prescribers). A pharmacist can also help in the development of medication-related documentation procedures, such as identification of abbreviations approved for use in the facility and can help guide the selection and use of medications in accordance with the authorized prescriber's orders, applicable state and federal requirements, manufacturers' specifications, characteristics of the resident population, and individual resident conditions.

Providing pharmaceutical consultation is an ongoing, interactive process with prospective, concurrent, and retrospective components. To accomplish some of these consultative responsibilities, pharmacists can use various methods and resources, such as technology, additional personnel (e.g., dispensing pharmacists, pharmacy technicians), and related policies and procedures.

Numerous recognized resources address different aspects of pharmaceutical services and medication utilization, such as:

- US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) Find Information about a Drug, Information on FDA-approved drugs released for sale on the market;
- The American Society of Health System Pharmacists (ASHP) http://www.ashp.org;
- The National Institutes of Health U.S. National Library of Medicine Medline Plus, https://medlineplus.gov/druginformation.html.
- AMDA - The Society for Post-Acute and Long-Term Care Medicine (American Medical Directors Association) https://paltc.org/;
- The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), https://www.nccmerp.org/;
- American Society for Parenteral and Enteral Nutrition (ASPEN), https://www.nutritioncare.org/.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

A. PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The regulation at 42 CFR 483.45 requires that the facility provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident. Facility procedures and applicable state laws may allow the facility to maintain a limited supply of medications in the facility for use during emergency or after-hours situations. Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident's condition. Factors that may help determine timeliness and guide acquisition procedures include:

- Availability of medications to enable continuity of care for an anticipated admission or transfer of a resident from acute care or other institutional settings;
- Condition of the resident including the severity or instability of his/her condition, a significant change in condition, discomfort, risk factors, current signs and symptoms, and the potential impact of any delay in acquiring the medications;
- Category of medication, such as antibiotics or analgesics;
- Availability of medications in emergency supply, if applicable; and
- Ordered start time/date for a medication.

Procedures should identify how staff, who are responsible for medication administration:

- Ensure each resident has a sufficient supply of his or her prescribed medications (for example, a resident who is on pain management has an adequate supply of medication available to meet his or her needs). At a minimum, the system is

expected to include a process for the timely ordering and reordering of a medication;
- Monitor the delivery and receipt of medications when they are ordered; and
- Determine the appropriate action, e.g., contact the prescriber or pharmacist, when a resident's medication(s) is not available for administration.

NOTE: Facility staff may encounter situations in which a medication is not available in the resident's supply or the facility's emergency medication supply and then decide to "borrow" medications from another resident's supply. This practice of borrowing medications from other residents' supplies is not consistent with professional standards and contributes to medication errors. Concerns about whether the facility has a system in place to ensure each resident has a sufficient supply of medications for timely administration should be cited under this tag Pharmacy Services (F755). However, if staff borrow any medication from another resident's supply due to failure to order the medication and/or not following the facility's system for reordering medications, refer to §483.21(b)(3), F658, Services Provided Meet Professional Standards. Instances of "borrowing," as described in this paragraph, would not be considered to be drug diversion.

Foreign Acquired Medications

It has been reported that some residents and/or facilities may be obtaining medications from foreign sources. Medications obtained from foreign sources may present safety issues since they have been manufactured or held outside of the jurisdiction of the United States (U.S.) regulatory system. These medications may not be safe and effective for their intended uses. The Federal Food, Drug, and Cosmetic Act (FFDCA) strictly limits the types of drugs that may be imported into the U.S. Medications imported into the U.S. may violate the FFDCA if they are unapproved by the FDA, labeled incorrectly, or dispensed without a valid prescription. The facility should, in collaboration with the pharmacist, assure that medications are provided or obtained from approved sources and do not violate the FFDCA.

If it is determined that the facility is providing/obtaining foreign medications that are not FDA approved for use by the residents, the State Agency must make referrals to appropriate agencies, such as the FDA; depending on the medication classification, the Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; and the State Licensure Board for Nursing Home Administrators.

B. PHARMACEUTICAL SERVICES PROCEDURES

The pharmacist, in collaboration with the facility and medical director, helps develop and evaluate the implementation of pharmaceutical services procedures that address the needs of the residents, are consistent with state and federal requirements, and reflect current standards of practice. These procedures address, but are not limited to, acquiring; receiving; dispensing; administering; disposing; labeling and storage of medications; and personnel authorized to access or administer medications.

Acquisition of Medications

Examples of procedures addressing acquisition of medications include:

- Availability of an emergency supply of medications, if allowed by state law, including the types or categories of medications; amounts, dosages/strengths to be provided; location of the supply; personnel authorized to access the supply; record keeping; monitoring for expiration dates; and the steps for replacing the supply when medications are used;
- When, how to, and who may contact the pharmacy regarding acquisition of medications and the steps to follow for contacting the pharmacy for an original routine medication order, emergency medication order, and refills;
- The availability of medications when needed, that is, the medication is either in the facility (in the emergency supply) or obtained from a pharmacy that can be reached 24 hours a day, seven days a week;
- The receipt, labeling, storage, and administration of medications dispensed by the prescriber, if allowed by state requirements;
- Verification or clarification of an order to facilitate accurate acquisition of a medication when necessary (e.g., clarification when the resident has allergies to, or there are contraindications to the medication being prescribed);
- Procedure when delivery of a medication will be delayed or the medication is not or will not be available; and
- Transportation of medications from the dispensing pharmacy or vendor to the facility consistent with manufacturer's specifications, state and federal requirements, and standards of professional practice to prevent contamination, degradation, and diversion of medications.

Receiving Medication(s)

Examples of procedures addressing receipt of medications include:

- How the receipt of medications from dispensing pharmacies (and family members or others, where permitted by state requirements) will occur and how it will be reconciled with the prescriber's order and the requisition for the medication;
- How staff will be identified and authorized in accordance with applicable laws and requirements to receive the medications and how access to the medications will be controlled until the medications are delivered to the secured storage area; and
- Which staff will be responsible for assuring that medications are incorporated into the resident's specific allocation/storage area.

Dispensing Medication(s)

Examples of procedures to assure compatible and safe medication delivery, to minimize medication administration errors, and to address the facility's expectations of the in-house pharmacy and/or outside dispensing pharmacies include:

- Delivery and receipt;
- Labeling; and
- The types of medication packaging (e.g., unit dose, multi-dose vial, blister cards).

Administering Medications
Examples of procedures addressing administration of medications include:

- Providing continuity of staff to ensure that medications are administered without unnecessary interruptions;
- Reporting medication administration errors, including how and to whom to report;
- Authorizing personnel, consistent with state requirements, to administer the medications, including medications needing intravenous administration (see Authorized Personnel section within this document);
- Assuring that the correct medication is administered in the correct dose, in accordance with manufacturer's specifications and with standards of practice, to the correct person via the correct route in the correct dosage form and at the correct time;
- Defining the schedules for administering medications to:

    - Maximize the effectiveness (optimal therapeutic effect) of the medication (for example, antibiotics, antihypertensives, insulin, pain medications, proton pump inhibitors, metered dose inhalers, and medications via enteral feeding tubes);
    - Prevent potential significant medication interactions such as medication-medication or medication-food interactions; and
    - Honor resident choices and activities, as much as possible, consistent with the person-centered comprehensive care plan;

- Defining general guidelines for specific monitoring related to medications, when ordered or indicated, including specific item(s) to monitor (e.g., blood pressure, pulse, blood sugar, weight), frequency (e.g., weekly, daily), timing (e.g., before or after administering the medication), and parameters for notifying the prescriber;
- Defining pertinent techniques and precautions that meet current standards of practice for administering medications through alternate routes such as eye, ear, buccal, injection, intravenous, atomizer/aerosol/ inhalation therapy, or enteral tubes. For example, for enteral feeding tubes, define procedures including but not limited to:

    - Types of medications that may be safely administered via enteral feeding tube;
    - Appropriate dosage forms;

- Techniques to monitor and verify that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) before administering medications; and
- Preparing drugs for enteral administration, administering drugs separately, diluting drugs as appropriate, and flushing the feeding tube before, between, and after drug administration, including the amount of water to be used for the flushing and administration of medications (and obtaining physician/practitioners order to address a resident with fluid restrictions).

NOTE: Enteral feeding tube practice recommendations may be found in ASPEN Safe Practices for Enteral Nutrition Therapy, https://aspenjournals.onlinelibrary.wiley.com/doi/full/10.1177/0148607116673053. References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

- Documenting the administration of medications, including:

  - The administration of routine medication(s), and, if not administered, an explanation of why not;
  - The administration of "as-needed" (PRN) medications including the justification and response;
  - The route, if other than oral (intended route may be preprinted on Medication Administration Record (MAR); and
  - Location of administration sites such as transdermal patches and injections;

- Providing accessible current information about medications (e.g., medication information references) and medication-related devices and equipment (e.g., user's manual) for all staff involved with the medication administration process;
- Clarifying any order that is incomplete, illegible, or presents any other concerns, prior to administering the medication; and
- Reconciling medication orders including telephone orders, monthly or other periodic recapitulations, and MAR, including who may transcribe prescriber's orders and enter the orders onto the MAR.

Disposition of Medications

Examples of procedures addressing the disposition of medications include:

- Timely identification and removal (from current medication supply) of medications for disposition;
- Identification of storage method for medications awaiting final disposition;
- Control and accountability of medications awaiting final disposition consistent with standards of practice;
- Documentation of actual disposition of medications to include: resident name, medication name, strength, prescription number (as applicable), quantity, date of

disposition, and involved facility staff, consultant(s) or other applicable individuals; and
- Method of disposition (including controlled medications) should prevent diversion and/or accidental exposure and is consistent with applicable state and federal requirements, local ordinances, and standards of practice;

Authorized Personnel

The facility may permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse.

The facility assures that all persons administering medications are authorized according to state and federal requirements, oriented to the facility's medication-related procedures, and have access to current information regarding medications being used by the residents, including side effects of medications, contraindications, doses, etc.

Examples of procedures addressing authorized personnel include:

- How the facility assures ongoing competency of all staff (including temporary, agency, or on-call staff) authorized to administer medications and biologicals;
- Training regarding the operation, limitations, monitoring, and precautions associated with medication administration devices or other equipment, if used, such as:

    - IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV or enteral feeding pump;
    - Blood glucose meters, including calibration and cleaning between individual residents; and
    - Using, maintaining, cleaning, and disposing of the various types of devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, and pill crushers;

- Identifying pharmacy personnel in addition to the pharmacist (e.g., pharmacy technicians, pharmacist assistants) who are authorized under state and federal requirements to access medications and biologicals.

C. SERVICES OF A LICENSED PHARMACIST

The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with a pharmacist. Whatever the arrangement or method employed, the facility and the pharmacist identify how they will collaborate for effective consultation regarding pharmaceutical services. The pharmacist reviews and evaluates the pharmaceutical services by helping the facility identify,

evaluate, and address medication issues that may affect resident care, medical care, and quality of life.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents' healthcare needs, goals, and quality of life that are consistent with current standards of practice, and that meet state and federal requirements. This should include, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services, including procedures to support resident quality of life such as those that support safe, individualized medication administration programs;
- Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])
- Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) which may include: determining competency of staff and facility-based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;

- Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;
- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;
- Strive to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants;
- Provide feedback about performance and practices related to medication administration and medication errors.

In addition, the pharmacist may collaborate with the facility and medical director on other aspects of pharmaceutical services including, but not limited to:

- Developing procedures and guidance regarding when to contact a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber;
- Developing the process for receiving, transcribing, and recapitulating medication orders;
- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors;
- Developing and implementing procedures regarding automated medication delivery devices or cabinets, if automated devices or cabinets are used, including:

the types or categories of medications, amounts stored, location of supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, method to ensure accurate removal of medications and the steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system;

- Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services including delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies, and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors;
- Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information; and
- Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families.

NOTE: This does not imply that the pharmacist must personally present educational programs.

D. CONTROLLED MEDICATIONS

Regulations require that the facility have a system to account for controlled medications' receipt and disposition in sufficient detail to enable an accurate reconciliation, and that the facility conduct a periodic reconciliation. This system should include, but is not limited to:

- Record of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date received, and the resident's name). However, in some delivery systems (e.g., single unit package medication delivery system or automated dispensing systems utilizing single-unit packages of medications that are not dispensed pursuant to a specific order), the resident's name may not be applicable;

NOTE: If permitted by, and in accordance with, state requirements, the facility may store some controlled medications in an emergency medication supply. The facility's policies and procedures must address the reconciliation of this supply, see 42 C.F.R. § 483.45(b)(2) and (3).

- Records of personnel access, usage, and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the MAR, proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;

- Periodic reconciliation of records of receipt, disposition, usage, and inventory for all controlled medications (as defined by facility procedures or when loss is identified). The reconciliation identifies loss or potential diversion of controlled medications so as to minimize the time between the actual loss or potential diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, periodic reconciliation should accommodate actual facility experience, such that if there is any evidence or even suspicion that diversion may be occurring, then that may dictate conducting the periodic reconciliation as frequently as daily. State or other federal requirements may specify the frequency of reconciliation.

    - If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them, and make referrals to law enforcement agencies as appropriate.
    - Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to blood borne pathogens. See §483.80 Infection Control, F880.
    - Liquid controlled medications are often dispensed in multi-dose containers which indicate approximate volume. The containers may also be opaque to protect the medication from light. It should be noted that absolute accuracy in tracking volume and use of liquid controlled medications may not be possible. The actual volume in these containers may be slightly over or under the manufacturer's stated volume depending on the shape and material of the container and the formulation of the medication such as thick liquid suspensions. The opaque container, measurement markings, manufacturer fill volume variation, and method for recording usage all make detection of diversion for liquid controlled medications more difficult. The general standard of practice for documenting usage of liquid controlled medications is to record the starting volume from the label, record each dose administered, subtract the dose administered from the previously recorded volume, and record the remaining amount. Any observed discrepancy between the recorded amount and what appears to be remaining in the container should be reported according to facility policy. Manufacturer's instructions may list the estimated volume variance (e.g., 30 mL plus or minus 2.5 mL). For liquid controlled medications, signs of diversion may include: an observable discrepancy between the written balances of remaining medication compared to the remaining amount in the bottle upon visual inspection; changes in the viscosity or color of the medication; reports of spills; and, as with other controlled medications, statements from a resident that the medication is not working.

- Disposal methods for controlled medications must involve a secure and safe method to prevent diversion and/or accidental exposure.

- Fentanyl transdermal patches present a unique situation given the multiple boxed warnings, and the substantial amount of fentanyl remaining in the patch after removal, creating a potential for abuse, misuse, diversion, or accidental exposure. Due to the life threatening risks associated with exposure to or ingestion of the patch, the Food and Drug Administration (FDA) and manufacturer instructions recommend consumers dispose of used fentanyl patches by folding the patch in half with the sticky sides together and flushing the patch down the sink or toilet, https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e15a7e9b-8025-49dd-9a6d-bafcccf1959f&type=display. . The Environmental Protection Agency bans flushing of pharmaceuticals if they are considered hazardous waste pharmaceuticals; fentanyl patches are not in this category, https://www.epa.gov/hw/defining-hazardous-waste-listed-characteristic-and-mixed-radiological-wastes#PandU. However, this method of disposal may not always be appropriate in nursing homes, particularly in areas where state or local laws restrict flushing of pharmaceuticals. Therefore, nursing homes may use drug disposal products or systems for fentanyl patches and other controlled medications as long as the facility can show that the product or system minimizes accidental exposure or diversion. Disposal in common areas or resident room trashcans or sharps containers are methods that would not prevent accidental exposure or diversion. Concerns related to fentanyl patch disposal which could lead to accidental exposure should be investigated at F689.

NOTE: The pharmacist is not required by these regulations to perform the reconciliation of medications, but rather to evaluate and determine that the facility maintains an accurate account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.

PROCEDURES §483.45

Use the Medication Administration Observation and the Medication Storage and Labelling Critical Element Pathway, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to, the provision of Pharmacy Services.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F755, the surveyor's investigation will generally show that the facility failed to:

- Provide medications and/or biologicals, as ordered by the prescriber, to meet the needs of each resident; or
- Ensure that only appropriate personnel administer medications, consistent with applicable state law and regulations; or
- Provide pharmaceutical services to meet each resident's needs which includes: acquiring, receiving, dispensing, accurately administering, or disposing of medications; or

- Provide or arrange for a licensed pharmacist who consults on all aspects of pharmaceutical services; or
- Establish systems to accurately reconcile controlled medications using acceptable standards of practice; or
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications in order to prevent loss, diversion, or accidental exposure.

DEFICIENCY CATEGORIZATION

In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level. For additional guidance, see also the Psychosocial Outcome Severity Guide at the CMS Nursing Homes Survey Resources website that can be accessed by visiting https://www.cms.gov/files/zip/survey-resources-10262022.zip.

Examples of noncompliance that demonstrate severity at Level 4 may include, but are not limited to:

- The facility, in collaboration with the pharmacist, failed to establish effective procedures to meet the needs of the residents, such as:

    - Assuring that pain medications were available to meet the needs of the resident-- The facility failed to obtain the routine regularly scheduled pain medicine for a resident who was to receive it every six hours. The investigation confirmed that the resident had been without pain medication for 2 days, the equivalent of 8 missed doses. This failure resulted in the resident complaining of excruciating, unrelieved pain (e.g., a pain score of 9 on a 10-point scale). The pain was all-consuming and overwhelming, leading to sleep loss, and a loss in interest and ability to perform activities of daily living.
    - Assuring that devices used to administer medications (such as IV pumps) were working properly, leading to an adverse consequence at the immediate jeopardy level, in which a resident received an incorrect dose of IV medication.

    - Provisions to assure that staff were trained or competent to use new medication-related devices (e.g., intravenous pump). This resulted in a resident receiving an inappropriate dose of medication requiring subsequent hospitalization.

Examples of Level 3, Actual harm (physical or psychosocial) that are not immediate jeopardy, may include, but are not limited to:

- The facility and the pharmacist failed to assure that procedures were developed and implemented so that all medication orders were processed consistently and accurately through the stages of ordering, receiving, and administering

medications (including transfer orders, admission orders, telephone orders, order renewals, and the MAR). For example, an ordering error led to an incorrect dose of a medication being administered and the resident experienced spontaneous bruising and frequent nosebleeds requiring medical intervention that was able to be performed in the nursing home.

- The facility failed to implement a system to consistently and accurately reconcile controlled medications. As a result, when staff attempted to administer pain medication to a resident, staff found no available medications despite documentation which showed the medications were available. The resident experienced mild to moderate pain that prevented the resident from attending physical therapy.

Examples of Level 2, No actual harm with a potential for more than minimal harm that is not immediate jeopardy, may include, but are not limited to:

- As a result of failure of licensed staff to supervise medication administration by authorized unlicensed personnel, two residents received their oral antibiotics late on one day, however the residents did not experience any harm.

- The facility failed to obtain or provide the services of a pharmacist or to collaborate with the pharmacist to assure that effective policies and procedures were established and implemented including, for example:

    - A resident did not receive medication for heartburn for two or more days and had difficulty sleeping during that time due to nocturnal heartburn. The level of discomfort did not interfere with the resident's participating in activities or performing activities of daily living.
    - As a result of failure to identify medications that should not be crushed for administration, a resident received a newly ordered medication that was crushed, contrary to the manufacturer's specifications. While the resident did not experience any harm, the potential for harm to the resident was present.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide routine and emergency drugs and biologicals to its residents creates the potential for more than minimal harm. This provision, along with pharmaceutical procedures and services are essential aspects of both process and outcome requirements.

Potential Tags for Additional Investigation

Examples of some of the related requirements that should be considered when concerns have been identified include the following:

- 42 CFR §483.12, F602, Right to be Free from Misappropriation/Exploitation

- Determine if the facility diverted a resident's medication, including, but not limited to, controlled substances for staff use or personal gain. If it is determined that a resident's medications were diverted, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; the state Medicaid Fraud Control Unit, and possibly the State licensure board for Nursing Home Administrators.

- 42 CFR §483.35, F725, Sufficient Staff and F726, Competent Staff
  - Determine if the facility had competent staff in sufficient numbers available to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.

- 42 CFR §483.45(g) and (h), F761, Labeling and Storage of Drugs and Biologicals
  - Determine if the facility properly labeled and stored all drugs and biological in accordance with currently accepted professional principles.

- 42 CFR §483.70(*g*), F841, Medical Director
  - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.

- 42 CFR §483.70(*h*), F842, Medical Records
  - Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.
- 42 CFR §483.75(g), F867, Quality Assessment and Assurance
  - If concerns regarding pharmaceutical services have been identified, determine whether the quality assessment and assurance committee has identified and responded to those concerns, as appropriate, and has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.